UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,982	05/08/2001	Pierre Marraccini	88265-4025	4965

7590 04/10/2003

Allan A. Fanucci
WINSTON & STRAWN
200 Park Avenue
New York, NY 10166

EXAMINER
KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/10/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/850,982	MARRACCINI ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/04/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *8 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7,15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-7 and 9-15; and SEQ ID NO: 1 encoding SEQ ID NO: 2 in Paper No. 15 is acknowledged.

Claim Objections

Claim 14 is objected to because of the following informalities: Claim 14 claims dependency from itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 9-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims an isolated nucleic acid derived from coffee encoding an endo-ß-mannanase involved in hydrolysis of polysaccharides that comprise pure or branched mannan molecules linked by beta 1-4 linkages, and a fragment thereof; and an isolated nucleic acid molecule that is homologous to and hybridizes to the nucleic acid of SEQ ID NO: 1.

Applicant describes a mannanase isolated from germinating coffee seedlings of SEQ ID NO: 1 encoding SEQ ID NO: 2 and a fragment of SEQ ID NO: 1 from nucleotide 11 to 1294 encoding a functional mannanase.

Applicant does not describe isolated nucleic acids derived from coffee involved in hydrolysis of polysaccharides that comprise pure or branched mannan molecules linked by beta 1-4 linkages other than SEQ ID NO: 1 and the 11-1294 nucleotide fragment of SEQ IDNO: 1.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.,* 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Claims 1-7 and 9-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1 and *E. coli* cells transformed therewith, does not reasonably provide enablement for an isolated nucleic acid derived from coffee encoding an endo-ß-mannanase involved in hydrolysis of polysaccharides that comprise pure or branched mannan molecules linked by beta 1-4 linkages, an isolated nucleic acid molecule that is homologous to and hybridizes to the nucleic acid of SEQ ID NO: 1, fragments thereof, and plants comprising said polynucleotides.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant broadly claims an isolated nucleic acid derived from coffee encoding an endo-ß-mannanase involved in hydrolysis of polysaccharides that comprise pure or branched mannan molecules linked by beta 1-4 linkages, an isolated nucleic acid molecule that is homologous to and hybridizes to the nucleic acid of SEQ ID NO: 1 under conditions of unspecified stringency, fragments thereof, and plants and coffee plant cells comprising said polynucleotides.

Applicant teaches the isolation of a coffee mannanase cDNA of SEQ ID NO: 1 by PCR amplification of a coffee cDNA library (Example 1 pages 10-16) and expression of coffee mannanase in *E. coli,* Ni-NTA column purification, and size correlation with mannanase expressed during seed germination (Example 3 page 24).

Applicant does not teach an isolated nucleic acid derived from coffee encoding an endo-ß-mannanase involved in hydrolysis of polysaccharides that comprise pure or branched mannan molecules linked by beta 1-4 linkages other than SEQ ID NO: 1, an isolated nucleic acid molecule that is homologous to and hybridizes to the nucleic acid of SEQ ID NO: 1 other than SEQ ID NO: 1, fragments thereof, and any plant comprising any of the said polynucleotides.

The isolation of DNA sequences having homology or that hybridize to a particular polynucleotide sequence introduces an element of unpredictability. The limitation is introduced in finding homologous regions that would adequately enable PCR amplification or southern hybridization and would entail using either degenerate primers or probes with limited sequence identity. Thus the screen for homologous sequences or sequences that hybridize to a particular

sequence under conditions of unspecified stringency would isolate many genes other than those of the instant claims. Fourgoux-Nicol *et al.*, 1999, Plant Molecular Biology, Vol. 40; pp. 857-872 teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2^{nd} paragraph). Fourgoux-Nicol *et al.* also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). The inherent unpredictability in isolating a sequence with some known function is illustrated in an example where a small number of changes to the coding region for a strict desaturase resulted in an enzyme with a hydroxylase activity and suggests that in general a small number of changes to a polynucleotide can account for a broad range of functional divergence (Broun P. *et al.* Science Vol. 282; 13 November 1998, pp. 1315-1317; Abstract lines 4-6 and p. 1317 column 1, lines 37-56).

Further, the unpredictability in obtaining a change in phenotype when attempting to modify metabolism in a plant is exemplified by the overexpression in potatoes of an ADPglucose pyrophosphorylase gene from *E. coli* wherein the increased activity resulted in an increased flux into the starch pathway but also resulted in an increase in the capacity of the tubers to degrade the starch in a manner proportionate to the increased flux, resulting in no detectable change in the phenotype (Sweetlove L. *et al.*, Biochem J., 1996; Vol. 320; pp. 493-498; see Abstract).

Furthermore, the unpredictability in making pharmaceutical compositions is exemplified in the tragic death of a volunteer in a human gene therapy trial. An unanticipated and hence unpredictable feature of the individuals' immune system resulted in massive organ failure when exposed to the 'pharmaceutical treatment' that could have been prevented if a simple blood test had been administered (Science, January 25, 2002; Vol. 295, pp. 604-604; third column page 604 to page 605 first column). Given the lack of guidance in the specification for making, isolating or testing both cosmetic and pharmaceutical composition is not enabled.

Given the lack of guidance for isolating any other polynucleotides comprising sequences homologous to SEQ ID NO: 1, or that hybridize to SEQ ID NO: 1 under conditions of unspecified stringency, the breadth of the claims, and given the unpredictability in the art, undue trail and error experimentation would be needed by one skilled in the art to isolate a multitude of non-exemplified mannanase encoding polynucleotides or fragments thereof, and to evaluate the effect of these polynucleotides, if any, in plant cells and plants transformed therewith. Undue experimentation would have been required to develop and evaluate gene therapy compositions or cosmetics. Therefore, the invention is not enabled for the scope set forth in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-13, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in the rejection.

At Claim 1, line 1, "derived" is indefinite. It is not clear what and how much has been changed in the derivation.

At Claim 1, line 2, "involved" is indefinite. It is not clear whether the involvement is direct or indirect, or involves a specific interaction.

At Claim 4, line 2, "derived" is indefinite. It is not clear what and how much has been changed in the derivation.

At Claim 4, line 3, "involved" is indefinite. It is not clear whether the involvement is direct or indirect, or involves a specific interaction.

At Claim 9, line 3, "involved" is indefinite. It is not clear whether the involvement is direct or indirect, or involves a specific interaction.

At Claim 13, line 3, "involved" is indefinite. It is not clear whether the involvement is direct or indirect, or involves a specific interaction.

Claim 15 recites the limitation "a fragment according to Claim 1" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-7, 9, 10, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorsboe M. *et al.* WO 97/20937 published June 12, 1997.

The claims are indefinite for reasons discussed supra, i.e. reciting polynucleotide sequences that are 'derived' from coffee and encode enzymes 'involved' in hydrolysis of

polysaccharides that comprise beta 1-4 linkages; and are broadly drawn to polynucleotides that have homology to and hybridize with SEQ ID NO: 1 or with fragments of SEQ ID NO: 1.

Jorsboe teaches a plant transformation vector comprising an alpha-glucosidase from coffee (page 41 lines 10-25) that acts upon galactomannans, having 1-4 beta linkages (page 1 line 7-8 and page 2 lines 29-30), transformed into *Agrobacterium tumefaciens* (page 42 lines 15-31), a dietary composition, guar gum, that includes a molecule that is homologous or hybridizes to SEQ ID NO: 1 (page 27 lines 26-32), and plants transformed with said vector comprising the alpha-glucosidase (page lines 5-28). Thus the reference teaches all the limitations of Claims 1-2, 6-7, 9, 10, and 12-15.

Claims 1-2, 6-7, and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Christgau S. *et al.* U.S. Patent 5,795,764 issued August 18, 1998.

The claims are indefinite for reasons discussed supra, i.e. reciting polynucleotide sequences that are 'derived' from coffee and encode enzymes 'involved' in hydrolysis of polysaccharides that comprise beta 1-4 linkages; and are broadly drawn to polynucleotides that have homology to and hybridize with SEQ ID NO: 1 or with fragments of SEQ ID NO: 1.

Christgau teaches a cDNA encoding an enzyme having mannanase activity (see Abstract) and a recombinant vector and microorganisms transformed therewith (column 14 lines 45-65). Also see attached sequence report. Thus the reference teaches all the limitations of Claims 1-2, 6-7, and 13-14.

Claims 1-2, 6-7, and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession number AF017144 submitted August 5, 1997.

The claims are indefinite for reasons discussed supra, i.e. reciting polynucleotide sequences that are 'derived' from coffee and encode enzymes 'involved' in hydrolysis of polysaccharides that comprise beta 1-4 linkages; and are broadly drawn to polynucleotides that have homology to and hybridize with SEQ ID NO: 1 or with fragments of SEQ ID NO: 1.

GenBank accession number teaches a mannanase encoding cDNA and inherently teaches a cloning vector and microorganism comprising said isolated polynucleotide. Thus, the reference teaches all the limitations of Claims 1-2, 6-7, and 13-14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 6-7, 9, 10, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorsboe *et al.* WO 97/20937 published June 12, 1997 in view of Stiles J. WO 98/06852 published February 19, 1998.

The claims are indefinite for reasons discussed supra, i.e. reciting polynucleotide sequences that are 'derived' from coffee and encode enzymes 'involved' in hydrolysis of polysaccharides that comprise beta 1-4 linkages; and are broadly drawn to polynucleotides that have homology to and hybridize with SEQ ID NO: 1 or with fragments of SEQ ID NO: 1.

Applicant broadly claims an isolated nucleic acid derived from coffee encoding an endo-ß-mannanase involved in hydrolysis of polysaccharides that comprise pure or branched mannan

molecules linked by beta 1-4 linkages, an isolated nucleic acid molecule that is homologous to and hybridizes to the nucleic acid of SEQ ID NO: 1, fragments thereof, and plants and coffee plant cells comprising said polynucleotides.

The teachings of Jorsboe are discussed supra.

Jorsboe does not teach transformation of coffee plants.

Stiles teaches transformation of coffee plants (see Abstract).

It would have been obvious at the time of Applicant's invention to modify the invention of Jorsboe to substitute transformation of guar to have an enzyme involved in hydrolysis of polysaccharides including mannan molecules having beta 1-4 linkages, with coffee transformation as taught by Stiles. One of skill in the art would have been motivated by the knowledge common in the art that transformation of coffee to have reduced precipitant during the treatment of coffee is a valuable product, and that one would have had a reasonable expectation of success of expressing genes in transformed plants and plant cells.

All claims are rejected.

Claims 3, 4, and 5 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO: 1 encoding the mannanase of SEQ ID NO: 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
April 4, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638